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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,423	06/28/2001	Ronald H. Chiarello	SYNGEN-06067	6875

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MEDLEN & CARROLL, LLP  
101 HOWARD STREET  
SUITE 350  
SAN FRANCISCO, CA 94105

[REDACTED] EXAMINER

LOEB, BRONWEN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1636

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/894,423	CHIARELLO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bronwen M. Loeb	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_ .
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 June 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Claims 1-4 are pending.

### ***Drawings***

1. The drawings are objected to because there are two sheets labeled "Fig. 2B"; the second sheet should be labeled "Fig. 2B continued". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. Figures 1A, 1A, 2A and 2B should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The disclosure is objected to because of the following informalities: On p. 9, line 13, it is unknown what "an activate label" means.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2 and 3 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 are rejected for referring to compounds listed in Tables. Claims should be complete in and of themselves. Incorporation by reference is only by necessity, not for convenience. See MPEP 2173.05(s).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1, 3 and 4 are rejected under 35 U.S.C. §102(b) as being anticipated by Snitman (USP 4,762,779). Snitman teaches reacting an oligonucleotide bound at its 3' end to a solid support with the linker  $[(CH_3)_2CH]_2NP(OCH_3)O(CH_2)_8NH(DMT)$  wherein DMT is a dimethoxytrityl group, to form a 5' amine functionalized oligonucleotide. This is then reacted with fluorescein isothiocyanate. In the process of reacting this with the fluorescein isothiocyanate, the protected amine group loses its protective DMT

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group. See entire document, especially col. 3, line 17- col. 4, line 16 and col. 8, line 67- col. 9, line 6.

8. Claims 1- 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Vinayak et al (USP 6,255,476 B1). Vinayak et al teach labeling an oligonucleotide bound at its 3' end to a polystyrene support by reacting the oligonucleotide with an amino-linker phosphoramidite reagent. The protected amino group is deprotected (thus deprotected) then reacted with an activated label, such as TAMRA-CO<sub>2</sub>H. Other labels taught for use in the method include: 6-FAM, rhodamines and fluoresceins. See entire document, especially col. 5, lines 46-63, col. 11, lines 16-58, cols. 13-16, col. 19, Example 3, col. 20, Example 5 and col. 22, Example 9. Absent evidence to the contrary it is assumed that the amino-linker phosphoramidite reagent is the same as that shown in col. 11, lines 30-40 except having DMT rather than MMT as the protecting group. This assumption is grounded in the knowledge that commercially-available DNA synthesis reagents typically employ DMT, that both groups are acid-labile protecting groups and also in the summary of the steps of a synthesis cycle taught by Vinayak et al in col. 10, lines 46-col. 11, line 15.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-4 are rejected under 35 U.S.C. §103(a) as being unpatentable over Snitman, in view of Vinayak et al. Snitman is applied as above to claims 1, 3 and 4. Snitman does not teach a linker that is identical to the two linkers disclosed in Tables 1, 2 and 3 in the instant application. Specifically, the moiety on the phosphate oxygen is a methyl group and not CH<sub>2</sub>CH<sub>2</sub>CHN. At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use any moiety at that position that could undergo beta-elimination. As such, the methyl is an equivalent of the CH<sub>2</sub>CH<sub>2</sub>CHN in the prior art. See for instance col. 11, lines 42-43 of Vinayak et al.

### ***Conclusion***

Claims 1-4 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

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Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Customer service for Tech Center 1600 may be reached at (703)-308-0198.

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

September 25, 2002

*Remmy Yucel*  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600